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DEP & REF  
PATENT TRADEMARK  
DIVISION 307



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

2004 AUG 23 PM 3:25

In re Patent Application of

YOKOI et al

Atty. Ref.: 249-118

Serial No. 09/680,514

TC/A.U.: 1647

Filed: October 6, 2000

Examiner: Spector

For: HG-CSF FUSION POLYPEPTIDE HAVING C-MPL  
ACTIVITY, DNA CODING FOR SAME AND METHODS OF  
TREATING ANEMIA USING SAME

\* \* \* \* \*

August 17, 2004

**Mail Stop 16**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**REFUND REQUEST**

The Office is requested to refund the undersigned's Deposit Account for the \$110 first month extension fee debited to Deposit Account No. 14-1140 in the monthly statement of July 2004, copy attached. A further explanation of the charge is requested in the event the Patent Office continues to believe the charge was appropriately made.

The noted fee should not have been charged to the undersigned's Deposit Account since the final Office Action dated April 7, 2004 (copy attached) is not an Ex Parte Quayle Action as indicated in the attached PTO PAIR Page printed by the undersigned on August 8, 2004. A Response to the noted final Office Action was timely filed (within three (3) months from the mailing date of the final Office Action). Accordingly, in view of the above and attached, the \$110 fee charged by the Patent

Adjustment date: 09/23/2004 SDIRETA1  
07/21/2004 6TRAMMEL 00000008 141140 09680514  
01 FC:1251 110.00 CR

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YOKOI et al  
Serial No. 09/680,514

CALIFORNIA  
DIVISION

Office to the undersigned's Deposit Account in the attached statement of July 2004 is

believed to be in error and refund of this amount is requested.

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Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_



B. J. Sadoff  
Reg. No. 36,663

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Arlington, VA 22201-4714  
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Facsimile: (703) 816-4100



**United States  
Patent and  
Trademark Office**



INVENTION DIVISION

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**Deposit Account Statement**

**Requested Statement Month:** July 2004  
**Deposit Account Number:** 141140  
**Name:** NIXON & VANDERHYE P.C.  
**Attention:** LENARD MITCHARD  
**Address:** 1100 N GLEBE ROAD  
**City:** ARLINGTON  
**State:** VA  
**Zip:** 22201-4714

DATE SEQ	POSTING REF TXT	ATTORNEY DOCKET NBR	FEE CODE	AMT	BAL
07/21 9	09680514	249-118 BJS	1251 ✓	\$110.00	\$14,731.98

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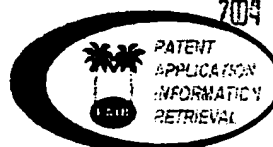
United States Patent and Trademark Office

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## PATENT APPLICATION INFORMATION RETRIEVAL



Search results as of: 8-8-2004::10:45:41 E.T.

Search results for application number: 09/680,514			
Application Number:	09/680,514	Customer Number:	23117
Filing or 371(c) Date:	10-06-2000	Status:	Response to Ex parte Quayle Action Entered and Forwarded to Examiner
Application Type:	Utility	Status Date:	07-21-2004
Examiner Name:	SPECTOR, LORRAINE	Location:	ELECTRONIC
Group Art Unit:	1647	Location Date:	-
Confirmation Number:	9035	Earliest Publication No:	-
Attorney Docket Number:	249-118	Earliest Publication Date:	-
Class/ Sub-Class:	536/023.5	Patent Number:	-
First Named Inventor:	Haruhiko Yokoi, Ibaraki, (JP)	Issue Date of Patent:	-
Title Of Invention:	hG-CSF fusion polypeptide having c-mpl activity, DNA coding for same and methods of treating anemia using same		

## Search Options

Display References
Foreign Priority
Image File Wrapper
Publication Review

File History	
Date	Contents Description
07-21-2004	Date Forwarded to Examiner
07-07-2004	Response after Ex Parte Quayle Action
07-07-2004	Request for Extension of Time - Granted
04-07-2004	Mail Ex Parte Quayle Action (PTOL - 326)
04-07-2004	Ex Parte Quayle Action
03-22-2004	Date Forwarded to Examiner
03-12-2004	Amendment/Argument after Notice of Appeal
03-12-2004	Request for Extension of Time - Granted
03-12-2004	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received
12-12-2003	Notice of Appeal Filed

PATENT MAINTENANCE  
DIVISION

12-12-2003	Request for Extension of Time - Granted
06-12-2003	Mail Final Rejection (PTOL - 326)
06-12-2003	Final Rejection
04-08-2003	Date Forwarded to Examiner 2004 AUG 23 PM 2:26
04-07-2003	Supplemental Response
03-24-2003	Date Forwarded to Examiner
03-21-2003	Supplemental Response
01-16-2003	Date Forwarded to Examiner
12-23-2002	Response after Non-Final Action
12-23-2002	Request for Extension of Time - Granted
01-16-2003	Correspondence Address Change
06-21-2002	Mail Non-Final Rejection
06-17-2002	Non-Final Rejection
06-17-2002	Mail Miscellaneous Communication to Applicant
06-17-2002	Miscellaneous Action with SSP
06-17-2002	Case Docketed to Examiner in GAU
06-14-2002	Case Docketed to Examiner in GAU
04-17-2002	Case Docketed to Examiner in GAU
10-06-2000	Information Disclosure Statement (IDS) Filed
10-06-2000	Preliminary Amendment
01-13-2001	Case Docketed to Examiner in GAU
12-28-2000	Application Dispatched from OIPE
12-28-2000	Correspondence Address Change
10-24-2000	IFW Scan & PACR Auto Security Review
10-06-2000	Initial Exam Team nn

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249-118



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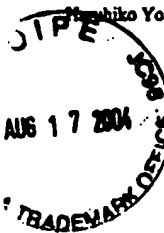
UNITED STATES DEPARTMENT OF COMMERCE  
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Alexandria, Virginia 22313-1450  
www.uspto.gov

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,514	10/06/2000	Shinichi Yokoi	249-118	9035

23117 7590 04/07/2004

NIXON & VANDERHYE, PC  
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ARLINGTON, VA 22201-4714



EXAMINER

SPECTOR, LORRAINE

ART UNIT PAPER NUMBER

1647

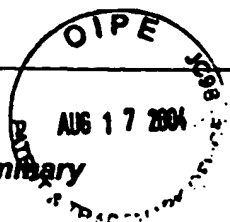
DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Final  
DOCKETED

CLT/MATTER # 249-118  
MAIL DATE 4-7-04  
DUE DATE July 7, 2004  
FINAL DEADLINE Oct 7, 2004  
DOCKETED BY pas/ta

# Office Action Summary



Application No. 08/880,514 DIVISION  
 Examiner  
 Lorraine Spector, Ph.D.

Applicant(s)  
 YOKOI ET AL.  
 Art Unit  
 1647

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -  
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.  
 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10-18 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 18 is/are rejected.  
 7) ☒ Claim(s) 10-17 is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

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## Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☒ The drawing(s) filed on 06 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) ☐ Notice of Informal Patent Application (PTO-152)  
 6) ☐ Other: \_\_\_\_\_

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**Part III: Detailed Office Action:**

Claims 10-15 are pending and under consideration.

Applicants request for consideration filed 1/12/2004 has been fully considered.

The new matter objection is withdrawn in view of applicants arguments.

**Claim Objections:**

37 C.F.R. §1.821(d) reads as follows:

(d) Where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

The claims and/or specification are not in full compliance with 37 C.F.R. §1.821(d), and should be amended to refer to the appropriate sequence identifier(s) (SEQ ID NO:). For example, see claims 10-12. As Table 1 is a sequence, reference to such sequence must be by reference to the appropriate sequence identifier. Wording such as "is replaced by an amino acid sequence of SEQ ID NO: X having a set of substitutions selected from the group consisting of those of Table 2a-j" or the equivalent. Correction is required.

The declaration under 37 CFR 1.132 filed 1/12/2004 is sufficient to overcome the rejection of claims 10-15 based upon Curtis in view of Yamasaki, de Sauvage and Souza because the data show a significantly higher induction of CD61 by the fusion protein than by either cytokine alone. CD61 is a marker for megakaryocyte differentiation. As evidenced by Kuby at page 41-42 and Mire-Sluis at pages 237 and 330 (both references made of record herein), one might have expected a synergistic effect on granulocyte (including neutrophil) differentiation using the fusion protein, but not on megakaryocyte differentiation. Further, the greater effect of



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the fusion protein *in vitro* (wherein kidney clearance is not an issue) relative to the two proteins in combination would not have been expected.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent Number 5,989,537 teaches and claims the use of TPO in combination with G-CSF for the stimulation of neutrophils. While this reference could have been applied in a rejection under 35 U.S.C. §103(a), the finding above applies equally to this reference.

Claims 10-15 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 16-18, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 16-18 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in the paper mailed 6/21/02 is hereby withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to controlling formation of 'colonies' *in vivo*. Cells are generally not regarded as forming colonies *in vivo*, hence the claim is indefinite. Deletion of the phrase "controlling formation of megakaryocyte colonies and neutrophil colonies and/or" would be remedial.

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**Advisory Information:**

Claims 10-17 are objected to.

Claim 18 is rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M. *Effective 1/21/2004, Dr. Spector's telephone number will be 571-272-0893.*

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623. *Effective 1/21/2004, Dr. Kunz' telephone number will be 571-272-0887.*

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). **NOTE:** If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

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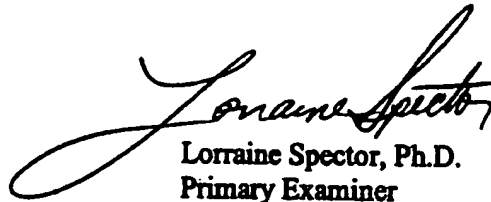
Application/Control Number: 09/680,514

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Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703) 872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228. *Effective 1/21/2004, Dr. Spector's fax number will be 571-273-0893.*



Lorraine Spector, Ph.D.  
Primary Examiner

O I P E

AUG 17 2004

## Notice of References Cited

Application/Control No.

09/880,514

Applicant(s)/Patent Under  
Reexamination  
YOKOI ET AL.

Examiner

Lorraine Spector, Ph.D.

Art Unit

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Page 1 of 1

## U.S. PATENT DOCUMENTS

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,989,537	11-1999	Holly et al.	424/85.1
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

## FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

## NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Data, Publisher, Edition or Volume, Pertinent Pages)
	U	"Cytokines", A. Mire-Sluis et al., ed., Academic Press, San Diego, 1998. Pages 237-238, 330-331.
	V	Janis Kuby, "Immunology", W.H. Freeman and Company, NY, 1992, pages 42 and 44.
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.06(e).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.